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parapharmatech

NATURE'S HEALTHIER
THICKENING OPTION



PRODUCT SPECIFICATIONS

PRODUCT

Gelmix, a hypoallergenic, USDA organic thickener for breast milk and infant formula, consists of an off-white fine powder that is tasteless, odorless and smooth when dissolved.¹ It is the first and only USDA organic thickener specifically formulated for pediatric use in America. Gelmix is free of corn, wheat, gluten, soy, whey, casein, lactose & dairy. It is also non-GMO, vegan & made with kosher pareve ingredients.

USES

Thickens breast milk and infant formula, facilitating the retention of nutrients in breast milk and formula that requires thickening. Thickening liquids is often recommended for the management of conditions present with gastroesophageal reflux (GER) and dysphagia.² Always consult a medical professional before thickening liquids to ensure it is appropriate for your infant's individual needs.

INGREDIENTS

Organic Tapioca Maltodextrin³, Organic Carob Bean Gum⁴, Calcium Carbonate⁵

CONTRAINDICATIONS

Not for use with infants under 6 pounds and/or born preterm currently under a corrected age of 2 weeks.⁶ Do not use if galactosemia or allergy to galactomannans is suspected. Stop using if rash or other allergic reaction develops, and consult a physician immediately. There are very few cases of allergies to galactomannans in academic literature. It is not typically recommended to use moderately thick liquids with infants and children less than 1 year old.⁷

SIDE EFFECTS

May cause transient gassiness and loose stools in first two weeks. This typically resolves on its own or by decreasing amount used.

¹ Gelmix is manufactured at a GMP (Good Manufacturing Practice) plant holding a USDA organic certification by Quality Certification Services (QCS). Each batch undergoes strict quality control testing with necessary precautions to ensure its safe use with infants.

² Only use under medical supervision. Suitable for breast milk and infant formulas. Not for use with pre-thickened formulas or in addition to other thickeners. These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. This product is not intended as a sole source of nutrition. For more info on thickening: Wenzl, Tobias G., et al. "Effects of thickened feeding on gastroesophageal reflux in infants: a placebo-controlled crossover study using intraluminal impedance." *Pediatrics* 111.4 (2003): e355-e359. Ojha, Shalini, and Jon Dorling. "Feed thickener for infants up to six months of age with gastro-oesophageal reflux." *The Cochrane Library* (2017). Cichero, Julie AY. "Thickening agents used for dysphagia management: effect on bioavailability of water, medication and feelings of satiety." *Nutrition Journal* 12.1 (2013): 54. McSweeney, Mairead E., et al. "Oral feeding reduces hospitalizations compared with gastrostomy feeding in infants and children who aspirate." *The Journal of pediatrics* 170 (2016): 79-84.

³ Organic tapioca maltodextrin is an easily digestible polysaccharide used as a food additive, derived from the cassava root. Maltodextrin is widely used in commercial thickeners, however most often it is derived from corn. Gelmix does not contain corn or any other common allergens.

⁴ Organic carob bean gum, also known as locust bean gum, is a natural seed gum. Carob bean gum has been safely used as an infant milk thickener to address digestive issues for decades. Theophilou, I. C., C. M. Neophytou, and A. Kakas. "Carob and its Components in the Management of Gastrointestinal Disorders." *J Hepatol Gastroenterol* 1 (2017): 005. Kawamura, Y. "Carob bean gum. Chemical and Technical Assessment for the 69th JECFA." (2008).

⁵ Calcium Carbonate is a naturally occurring mineral and is added for its anti-caking properties to improve the consistency of Gelmix.

⁶ To calculate corrected age, the infant's chronological age is reduced by the number of weeks born before 40 weeks of gestation. 2 weeks corrected age is also referred to as 42 weeks postmenstrual age. For more info on safety of use for neonates: Constable, Anne, et al. "An integrated approach to the safety assessment of food additives in early life." *Toxicology Research and Application* 1 (2017): 2397847317707370. Meunier, Leo, et al. "Locust bean gum safety in neonates and young infants: an integrated review of the toxicological database and clinical evidence." *Regulatory Toxicology and Pharmacology* 70.1 (2014): 155-169.

⁷ Moderately thick liquids are more difficult to pass through a nipple/teat and may be too thick for infant use. This difficulty may increase risk of dehydration due to poor oral intake. Cichero, Julie AY, et al. "The need for international terminology and definitions for texture-modified foods and thickened liquids used in dysphagia management: foundations of a global initiative." *Current physical medicine and rehabilitation reports* 1.4 (2013): 284.



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INSTRUCTIONS FOR PREPARATION AND USE

Always wash hands thoroughly with soap & water and sanitize bottle and/or pitcher before preparation. For best results, mix Gelmix powder into lukewarm liquid (about 100°F) per dosage recommendations below. Mix well until powder is completely dissolved. Allow to thicken 5 minutes, then mix again before serving. Always test temperature before feeding. Discard leftover preparation.

DOSAGE RECOMMENDATIONS ⁸

1 SLIGHTLY THICK (AKA THIN NECTAR)

Add 2.4g* Gelmix for every 5-6 ounces of liquid

2 MILDLY THICK (AKA NECTAR)

Add 2.4g Gelmix for every 3-4 ounces of liquid

3 MODERATELY THICK ** (AKA HONEY)

Add 2.4g Gelmix for every 2 ounces of liquid

*Gelmix jars include a 1.2g scoop (1/2 serving) for mixing smaller increments, 2.4g equals TWO scoops or a single serving 2.4g packet.

**Moderately thick liquids are more difficult to pass through a nipple/teat and are NOT typically recommended for infants. This difficulty may increase risk of dehydration due to poor oral intake.

TIPS FOR USE

- Freshly expressed breast milk at body temperature, or warmed to about 100F, is sufficiently warm. Take care not to excessively heat liquids; excessive heat may cause the Gelmix to clump and may reduce the nutrient balance of infant milk.

- Gelmix may be prepared with most liquids in advance; always follow storage instructions of the prepared liquid and discard after 24 hours.

Supplement Facts

Serv. Size 2 scoops (2.4g)

Servings Per Container 52

Amount/serving	%DV for Infants
Calories 10	
Total Carb. 2g	*
Fiber 1g	*

* Daily Value (DV) not established

Ingredients: Organic Tapioca Maltodextrin, Organic Carob Bean Gum, Calcium Carbonate

⁸ Designed for use with IDDSI framework (www.iddsi.org). Tests performed by Parapharma Tech.

⁹ When thickening is deemed medically necessary, some insurance providers do cover Gelmix under HCPCS Code B4100 under Durable Medical Equipment (DME) billing. Check with your insurance carrier or your local state Medicaid/Medicare office for specific coverage regulations and restrictions. Gelmix does not carry an NDC code. NDC codes are reserved only for OTC and prescription drugs, not dietary supplements.

SERVINGS PER CONTAINER

GELMIX 4.4oz Jar (125g)

contains 52 servings, thickening 312 fl oz to Slightly Thick; **MSRP \$24.95**

GELMIX 2.4g Stick Pack Box

contains 30 individual serving packets, thickening 180 fl oz to Slightly Thick; **MSRP \$19.95**

AVAILABILITY ⁹

Gelmix is available at select local retailers, pharmacies and DME providers. Visit our website for a current list of retailers near you.

Gelmix may also be purchased online at gelmix.com or Amazon Prime.

Retailers and healthcare facilities are eligible to purchase Gelmix at a wholesale rate. Contact us for more information and pricing.

CONTACT

Parapharma Tech, LLC

14149 NW 8TH ST
SUNRISE FL 33325-6268

866-950-7278

contact@gelmix.com